GUIDANCE FOR REVIEW OF CASES OF POSSIBLE SUSPENSION OR REVOCATION OF MAMMOGRAPHY FACILITY CERTIFICATES UNDER THE MAMMOGRAPHY QUALITY STANDARDS ACT, 42 U.S.C. § 263(b)

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Mammography Standards Branch
Division of Mammography Quality and Radiation Programs
Office of Health and Industry Programs

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Comments and suggestions may be submitted at any time for Agency consideration to, Mammography Standards Branch, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Chet Trybus by telephone at (301) 594-3772 or by electronic mail at cgt@fdadr.cdrh.fda.gov.

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Food and Drug Administration
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UNITED STATES FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF HEALTH AND INDUSTRY PROGRAMS
DIVISION OF MAMMOGRAPHY QUALITY AND RADIATION PROGRAMS

INTRODUCTION

This guidance document reflects the agency's current thinking on procedures for review and decision making for potential cases of suspension or revocation of mammography certificates under the Mammography Quality Standards Act of 1992 (MQSA or the Act). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

BACKGROUND

MQSA, at subsection 263b(i), makes provision for suspension or revocation of certificates issued under the Act. Suspension and revocation may only take place after the Food and Drug Administration (FDA) has provided reasonable notice and an opportunity for a hearing to the owner or operator of a facility, unless FDA finds that continued operation of a facility presents a serious risk to human health (or that other conditions specified at 263b(i)(2)(A) have been met). In such case, a certificate may be suspended prior to a hearing. If FDA suspends a certificate prior to a hearing, FDA will provide an opportunity for a hearing within 60 days of the date of suspension, and will render a decision within 90 days of the date of suspension.

Suspension and revocation cases are rare. Since implementation of MQSA on October 1, 1994, through September 1997, FDA has only had to review two suspension cases and no revocation cases. One suspension case, following revocation of a facility's accreditation by its accreditation body, led to suspension prior to a hearing. The other, a formal request for suspension from an FDA field office, was found to be insufficient for suspension.

The following procedures have been written for review of possible suspension cases. In the event that a possible revocation case requires review, the general procedure for suspension may be followed. However, the procedures and personnel may have to be modified as a function of the circumstances, which at present are largely unpredictable.

PROCEDURES

The procedures below should be followed in the event that the Division of Mammography Quality and Radiation Programs (DMQRP) receives either:

1. a formal request for suspension of a facilities certificate, e.g., from an FDA field office,

2. notification of suspension or revocation of accreditation by an accreditation body found by FDA to be justified by violation of applicable quality standards[1], or

3. other information that strongly suggests that suspension should be considered.

SCREENING PROCESS

The person(s) receiving the information above will immediately notify their Branch Chief, who will notify the Division and Deputy Division Directors that a potential certificate suspension or revocation case is to be evaluated. A screening committee consisting of a compliance case evaluation officer (CCO)[2], certification officer (CO)[3], and the appropriate accreditation body liaison officer (ABLO)[4] assigned by their Branch Chiefs will be convened.

The screening committee shall review all available information pertaining to the case, and determine whether there is reason to convene an ad hoc Certificate Suspension Case Committee (Committee) to conduct a further investigation. If convened, the Committee shall conduct an investigation, and formulate and present a recommendation to Division management, whether the facility's certificate should be suspended or revoked, a corrective action plan should be submitted and implemented, or other sanctions should be imposed. Summary minutes of all committee meetings shall be prepared and retained.

All investigations and determinations must be completed in an expeditious manner because one outcome may be a determination that continued operation of the facility may constitute a health hazard. In such cases it may be necessary for FDA to suspend a certificate prior to a hearing, and time will be of the essence to protect the public health.

When the screening committee determines whether or not there is reason to convene a Committee, they shall so notify the Division Director, Deputy Director and their respective Branch Chiefs. Initial notification may be oral, but notification for the record should be made by memo or E-mail, and must contain summary minutes of the meeting including the reasons for the decision.

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[1] The Interim Regulations state at 21 CFR 900.13(a):

> "*Accreditation*. If a facility's accreditation is revoked by an accreditation body, the facility's certificate shall remain in effect until such time as determined by the agency on a case-by-case basis after an investigation into the reasons for the revocation. If FDA determines that the revocation was justified by violations of applicable quality standards, FDA will revoke or suspend the facility's certificate and/or require the submission of a corrective action plan, whichever action will protect the public health in the least burdensome way."

[2] Assigned by the Inspection Support Branch

[3] Assigned by the Information Management Branch

[4] Assigned by the Mammography Standards Branch

AD HOC CERTIFICATE SUSPENSION CASE COMMITTEE REVIEW

If an ad hoc Certificate Suspension Case Committee is to be convened, the following actions shall be taken:

1. The Committee will be formed, and will normally consist of the screening Committee members, the Chiefs or additional assigned representatives of the Mammography Standards, Inspection Support, and Information Management Branches, one or more radiologists, and other persons specifically concerned with issues in the case. The CCO or the ABLO will serve as committee chair, as appropriate, based upon the initiating event.

2. The Committee shall create an administrative record file for the case. The administrative record must contain all documents, summary minutes of all meetings, and any other information needed to provide a complete documented account of the case. This will be provided to the Office of the Chief Counsel (OCC) in the event that a hearing becomes necessary.

3. The Committee will meet and initiate an investigation to determine how FDA should respond to the case. The investigation will include identification and collection of all available information that pertains to determining whether or not submission and implementation of a corrective action plan is appropriate, whether sanctions should be imposed, or whether the facility's certificate should be suspended, and if the latter, whether the suspension should be prior to a hearing.

4. At a minimum, the Committee will collect the following information:

    a. The summary minutes of the screening committee's meeting, including the basis for convening the Committee, and all documents used in making that determination.

    b. A summary accreditation history from the accreditation body (ies), including all applicable correspondence to and from the facility, other than actual applications for accreditation, any reports of failure during the accreditation process, and a discussion of any problems encountered with the facility during accreditation.

    c. If it exists, a history of State interactions with the facility, e.g., inspection reports, violations of state regulations etc.

    d. The accreditation and certification history from the FDA data base.

    e. A summary report of all MQSA inspections, including a complete report of the most recent inspection and others as requested by the Committee.

f. All other information or correspondence that may be pertinent to the case.

5. Copies of all information collected or added at a later time shall be provided to all Committee members for their review and made part of the administrative record.

6. A meeting of the Committee shall be called[5] as soon as possible but not more than 5 working days after the meeting described in 3 above. The Committee shall determine whether to recommend suspension of the facility's certificate, submission and implementation of a corrective plan or other sanctions If the Committee recommends suspension, they must include a recommendation of whether or not to suspend the certificate before a hearing is held.

   If the facility's accreditation has been revoked and, pursuant to 21 CFR 900.13(a) the Committee determines that the revocation was justified by violations of applicable quality standards, the recommendation must be to revoke or suspend the facility's certificate and/or require the submission and implementation of a corrective action plan, whichever action will protect the public health in the least burdensome way.

   The recommendation will be submitted, at the earliest possible time, to DMQRP management for review and concurrence. If the recommendation is to suspend the facility's certificate or to impose sanctions, the recommendation will also be submitted, at the same time, to OHIP management and OCC.

MANAGEMENT DECISION AND FINAL ACTIONS

If OCC and Division/Office management concur with the Committee's recommendation, it will be implemented. If OCC or management do not concur, appropriate personnel will confer to establish a consensus on the recommendations and make a final decision.

If the decision is to suspend the certificate, the Inspection Support Branch will prepare an appropriate letter to the facility, to be reviewed by Division and Office management and OCC. The letter will be prepared for the signature of the Director, Office of Health and Industry Programs, and will inform the facility of the decision, of its right to a hearing, whether or not suspension will be implemented prior to a hearing, the actions the facility must take, and the facility's further rights to appeal the decision.

If the decision is to impose sanctions, the Inspection Support Branch will interact with the Office of Compliance to implement the sanction.

If the decision is for a corrective action plan to be submitted and implemented, the Standards

[5] A quorum of the Committee, consisting of at least 5 members including one representative of each of the three branches and a radiologist, shall be present at all Committee meetings.

Branch will confer with the facility's accreditation body to establish a consensus on the corrective actions the facility must take. Depending on the circumstances of the case, either FDA or the facility's accreditation body will inform the facility of the need for submission and implementation of a corrective action plan, and monitor all corrective actions.